PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PU03103-PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2004/001872	International filing date *(day/month/year)* 15-12-2004	Priority date *(day/month/year)* 23-12-2003
International Patent Classification (IPC) or national classification and IPC See Supplemental Box		
Applicant AMERSHAM BIOSCIENCES AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
13-06-2005	15-03-2006
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Form PCT/IPEA/409 (cover sheet) (April 2005)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Cover sheet

International patent classification (IPC)

B01D57/02 (2006.01)
G01N 27/26 (2006.01)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/001872

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____ ,
which is the language of a translation furnished for the purposes of:

- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☐ the international application as originally filed/furnished

☒ the description:

pages 1-7 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☒ the claims:

pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* 1-2 received by this Authority on 10-02-2006
pages* _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing *(specify)*: _____
- ☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/001872

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-17	YES
	Claims		NO
Inventive step (IS)	Claims	1-17	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

This report is based upon the amended claims filed with the letter of 10-02-2006. The amendments consist of the following technical features:
1) the IPG gel is an acidic interval IPG gel
2) the support is placed between the cathode and the cathode side of the gel.

Documents cited in the International Search Report:

D1: WO 96/27787 A1
D2: US 6376231 B1
D3: WO 99/12025 A1
D4: WO 98/00706 A1
D5: Biotechnol. Prog, Volume 15, 1999, Xianfang Zeng et al, "REVIEW: MEMBRANE CHROMATOGRAPHY: PREPARATION AND APPLICATIONS TO PROTEIN SEPARATION".

In the International Search Report, D1-D4 were cited as category X documents. However, none of them are considered relevant regarding novelty or inventive step with respect to the amended claims.

D1 discloses the use of a positively charged support for applying sample to the cathode side of an electrophoretic gel (refer to page 5, line 1-18, page 11, line 24 - page 12, line 9, figure 5b and claims 7 and 14).

D2 relates to an applicator paper for sample application to an electrophoretic gel. The applicator consists of chromatographic cation exchange material as opposed to the

.../...

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of: Box V

positively charged support (i.e. anion exchange material) used in the present invention. However D2 also discloses a comparative example where DEAE-cellulose is used as applicator paper.

Also documents D3 (page 2, line 9 - page 3, line 2) and D4 (page 6, line 1-19, page 15, lines 1-14 and pages 26-27) disclose examples of positively charged membranes for sample application to electrophoretic gels.

NOVELTY:

The invention as defined by independent claims 1, 12 and 16 differs from what is disclosed by D1-D4 in that it relates to sample application to acidic interval IPG gels.

The claimed invention is thus novel.

INVENTIVE STEP:

The present invention solves the problem of avoiding protein precipitation, which may occur when loading samples to acidic interval IPG gels from the anodic side.

None of D1-D4 solves or discusses this problem. Therefore, none of D1-D4, or any relevant combination thereof, would lead a person skilled in the art to the invention claimed in claims 1-17.

Thus the claimed invention is considered to involve an inventive step.

INDUSTRIAL APPLICABILITY:

The invention is industrially applicable.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

For clarity, the meaning of the abbreviations DEAE, Q and QAE could be incorporated in claims 5, 6, 9, 15 and 17.

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AMENDED CLAIMS

1. Use of a hydrophilic support derivatised with positively charged groups, for sample application to an acidic interval IPG (immobilised pH gradient) gel, wherein the support is placed between the cathode and the cathode side of the gel.

2. Use according to claim 1, wherein the support is made of regenerated cellulose, dextran, agarose, polyvinylalcohol, polyether sulfone, polysulfone, cellulose acetate, polyurethane, polyamide, nylon or other types of membranes and composite membranes.

3. Use according to claim 1 or 2, wherein the positively charged groups are cation groups.

4. Use according to claim 3, wherein the cation groups are quaternary groups.

5. Use according to claim 4, wherein the quaternary groups are QAE or Q groups.

6. Use according to claim 5, wherein the cation groups are DEAE- groups.

7. Use according to any of the above claims, wherein the IPG gel is a pre-swollen RTG (ready-to-go) gel.

8. Use according to one or more of the above claims, wherein the support is made of regenerated cellulose derivatised with quaternary groups.

9. Use according to claim 8, wherein the quaternary groups are Q-groups.

10. Use according to one or more of the above claims, wherein the sample is applied in preparative amounts.

11. Use according to one or more of the above claims, as a first step in 2D electrophoresis.

12. Kit comprising a positively charged sample application support according to any of the above claims and an acidic interval IPG gel or strip.

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13. Kit according to claim 12, wherein the IPG gel is a RTG-gel.

14. Kit according to claim 12, wherein the acidic interval is pH 3.5-5.

15. Kit according to one or more of the claims 12-14, wherein the support is made of regenerated cellulose derivatised with Q-groups.

16. Sample applicator for acidic interval IPG electrophoresis, comprising regenerated cellulose derivatised with cation groups.

17. Sample applicator according to claim 16, comprising regenerated cellulose derivatised with Q-groups.